Exhibit

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,246	09/14/2000	Thomas A. Berson	09103-01620US	2046

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER
KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 10/28/2002

Response Due 1/28/03 SSP

Please find below and/or attached an Office communication concerning this application or proceeding.

ENTERED 1/28 SP

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/662,246	BERSON ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30 and 31* is/are allowed.

6)☒ Claim(s) *1-29 and 32-38* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 4, 14, 17, and 37-38 rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,126,613 to Edwards et al. Edwards et al. teaches a spirometer which provides several different types of breathing measurements and a patient electronic signature device for identifying the patient using the spirometer. (column 2, lines 48-59 of Edwards et al.). In regard to claims 1 and 14, the data relating to the sensor which is created in the digital signature is the identity of the patient who is using the spirometer.

3. Claims 1-4, 14-17, 23-26, 28-29, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by International Application Publication WO 97/29678 to Osadchy et al. Osadchy et al. teaches a microcircuit in a catheter connector which has a calibration code. The code is encrypted using an RSA encryption scheme using a public key and a private key. (page 6, lines 18-31 of Osadchy et al.). In regard to claims 1 and 14, the catheter provides the physiological signal and the microcircuit has that calibration code which is data relating to the catheter and contains a digital signature in the form of the RSA encryption scheme. Osadchy et al. teaches that the calibration data can be for the physiological sensor. (page 22, lines 20-22 of Osadchy et al.). In regard to claims 23 and 29, the monitor stores the physiological information, the key and verification program for the encryption code, and a transfer circuit.

4. Claims 1-10, 14-22, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,298,255 to Cordero et al. Cordero et al. teaches a sensor system which includes a biopotential signal monitor, a smart sensor and the accompanying hardware and software interface which authenticates the source and validity of the smart sensor and also verifies that the smart sensor meets various criteria for use. (Abstract of Cordero et al.). In regard to claims 1 and 3, digital signature algorithms such as El Gamal and RSA public key encryption algorithms can be used. (column 17, lines 35-55 of Cordero et al.). In regards to claim 6-8 and 20-22, the source of the smart sensor 2 is authenticated and the integrity of its data validated by using a

"digital signature." Signature generation requires the use of a "hash" function (h). In the case of a public key algorithm, the digital signature is generated using a signature generation function which typically uses both the private and public keys as well as the hashed message. (column 15, line 63 to column 16, line 37 of Cordero et al.).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5-10 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. as applied to claims 4 and 14, and further in view U.S. Patent 6,170,058 to Kausik. Osadchy et al. does not teach the use of a symmetric key contained within the digital signature. Osadchy et al. teaches that any public key encryption/decryption methods known in the art may be used. (page 6, lines 27-29 of Osadchy et al.). Kausik teaches a method of encryption/decryption that can be used with existing public key signature methods such as RSA. (column 4, lines 25-44 of Kausik). Such a method falls within the scope of the other methods using any public key encryption/decryption method. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the encryption/decryption method of Kausik for the

encryption/decryption method of Osadchy et al. since Osadchy et al. teaches that other methods can be used and Kausik teaches such methods. Kausik further teaches that the selection of cryptographic techniques can be chosen from asymmetric or symmetric encryption, CRCs, hashes, and message digests. The choice of the most appropriate encryption algorithm will depend on the designers' preference, the amount of data to be encrypted, desired computational time for the encryption process; and the desired complexity of the encryption process. This provides a clear suggestion that the desired encryption/decryption process can be modified and that the determination of the most appropriate encryption/decryption process by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

7. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. as applied to claim 1, and further in view U.S. Patent 4,942,877 to Sakai et al. Osadchy et al. does not teach that the smart sensor is applied to pulse oximeters. Osadchy et al. teaches that the calibration data can be used for physiological sensors. (page 22, lines 20-22 of Osadchy et al.). It is well known in the art that pulse oximeters are types of physiological sensors which have memories associated with them. (Abstract of Sakai et al.). Sakai et al. discloses that such memories store calibration data of the sensor and the operating parameters of the sensor. Since Osadchy et al. implies that the device can be used to store calibration data for physiological sensors and oximeters are well-known sensors that utilize such technology, it would be obvious for one with ordinary skill in the art to

conclude that such a memory could also be used in oximetry. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the calibration memory of Osadchy et al. in the oximeter of Sakai et al. since Osadchy et al. implies that the calibration data can be applied to physiological sensors and Sakai et al. teaches one such sensor.

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. as applied to claim 23, and further in view U.S. Patent 6,307,938 to Matyas, Jr. et al. Osadchy et al. does not teach the use of the Rabin-Williams signature. Osadchy et al. teaches that any public key encryption/decryption methods known in the art may be used. (page 6, lines 27-29 of Osadchy et al.). Osadchy et al. further teaches that RSA algorithms can be used. (page 6, lines 27-29 Osadchy et al.). Matyas, Jr. et al. teaches that the RSA method and Rabin-Williams public key algorithms are known. (column 10, lines 54-62 of Matyas, Jr. et al.). Both methods are public key cryptographic algorithms which perform the same tasks and are functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the Rabin-Williams method for the RSA method of Osadchy et al. since they are functionally equivalent and Osadchy et al. teaches any known public key encryption/decryption or digital signature methods can be employed.

9. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO 97/29678 to Osadchy et al. as applied to claims 1, 14, and 29, and further in view U.S. Patent 4,942,877 to Sakai et al., and further in view of U.S. Patent 5,995,855 to Kiani et al. Osadchy et al. does not teach that the smart sensor is applied to pulse oximeters. Osadchy et al. teaches that the calibration data can be used for physiological sensors. (page 22, lines 20-22 of Osadchy et al.). It is well known in the art that pulse oximeters are types of physiological sensors which have memories associated with them. (Abstract of Sakai et al.). Sakai et al. discloses that such memories store calibration data of the sensor and the operating parameters of the sensor. Since Osadchy et al. implies that the device can be used to store calibration data for physiological sensors and oximeters are well-known sensors that utilize such technology, it would be obvious for one with ordinary skill in the art to conclude that such a memory could also be used in oximetry. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the calibration memory of Osadchy et al. in the oximeter of Sakai et al. since Osadchy et al. implies that the calibration data can be applied to physiological sensors and Sakai et al. teaches one such sensor. Osadchy et al. does not teach that the memory associated with the sensor is mounted in an adapter coupled between the sensor and monitor. Osadchy et al. does teach that the microcircuit is located between the sensor and the monitor. It is well known in the art that calibration circuitry relating to the sensor can be placed in a variety of locations such as in a connector (as seen in U.S. Patent 5,660,657 to Nierlich et al.), or in an adapter which is used to translate

sensor information to different monitors (as seen in Kiani et al.). The placement of the identification circuitry depends on the size of the sensor, the cost of replacing sensors, and the desired flexibility of using the sensor with different monitors. Such design considerations provide a clear suggestion that the most appropriate place for the identification circuitry can be modified and that the determination of the most appropriate location by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

10. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,298,255 to Cordero et al. as applied to claim 1. Cordero et al. does not teach that the smart sensor is applied to pulse oximeters. Cordero et al. teaches that the invention is related to electrophysiological sensors. (column 1, lines 9-12 of Cordero et al.). Cordero et al. teaches four related patents that disclosed coded sensors in oximeters. (column 1, line 59 to column 2, line 32 of Cordero et al.). Cordero et al. implies that these devices would be improved by using the smart sensor configuration to store specific data concerning the sensor itself, the date of expiration, sensor serial number, calibration data, and configuration data. (column 3, lines 6-20 of Cordero et al.). From this information, one with ordinary skill in the art would obviously conclude that the smart sensor configuration can be applied to oximeters. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the smart sensor configuration in an oximeter since Cordero et al. implies that oximeters would benefit from such a configuration.

11. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,298,255 to Cordero et al. as applied to claims 1 and 14 and further in view of U.S. Patent 5,995,855 to Kiani et al. Cordero et al. does not teach that the memory associated with the sensor is mounted in an adapter coupled between the sensor and monitor. Cordero et al. does teach that the sensor identification circuitry is located between the sensor and the monitor. It is well known in the art that identification circuitry relating to the sensor can be placed in a variety of locations such as on the sensor (as seen in Cordero et al.), in a connector (as seen in U.S. Patent 5,660,657 to Nierlich et al.), or in an adapter which is used to translate sensor information to different monitors (as seen in Kiani et al.). The placement of the identification circuitry depends on the size of the sensor, the cost of replacing sensors, and the desired flexibility of using the sensor with different monitors. Such design considerations provide a clear suggestion that the most appropriate place for the identification circuitry can be modified and that the determination of the most appropriate location by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

12. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,298,255 to Cordero et al. in view of U.S. Patent 5,995,855 to Kiani et al. Cordero et al. teaches a sensor system which includes a biopotential signal monitor, a smart sensor and the accompanying hardware and software interface which authenticates the source and validity of the smart sensor and also verifies that the smart

sensor meets various criteria for use. (Abstract of Cordero et al.). Digital signature algorithms such as El Gamal and RSA public key encryption algorithms can be used. (column 17, lines 35-55 of Cordero et al.). The source of the smart sensor 2 is authenticated and the integrity of its data validated by using a "digital signature." Cordero et al. does not teach that the memory associated with the sensor is mounted in an adapter coupled between the sensor and monitor. Cordero et al. does teach that the sensor identification circuitry is located between the sensor and the monitor. It is well known in the art that identification circuitry relating to the sensor can be placed in a variety of locations such as on the sensor (as seen in Cordero et al.), in a connector (as seen in U.S. Patent 5,660,657 to Nierlich et al.), or in an adapter which is used to translate sensor information to different monitors (as seen in Kiani et al.). The placement of the identification circuitry depends on the size of the sensor, the cost of replacing sensors, and the desired flexibility using the sensor with different monitors. Such design considerations provide a clear suggestion that the most appropriate place for the identification circuitry can be modified and that the determination of the most appropriate location by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

Allowable Subject Matter

13. Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 30-31 are allowed.

15. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a field of data with a mandatory/optional bit flag from a memory that is associated with a sensor and located external to a monitor.

Response to Amendment

16. The declaration filed on 8/26/2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Cordero et al. reference. The Cordero et al. reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

17. The declaration filed on 8/26/2002 under 37 CFR 1.131 is sufficient to overcome the von der Ruhr et al. reference.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,842,977 to Lesho et al. discloses a temperature monitor with a calibration signature imposed on the signal telemetered from the environment in which the monitor is enclosed (column 2, lines 21025 of Lesho et al.)..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Assistant Examiner
Art Unit 3736
October 24, 2002

ERIC F. WINAKUR
PRIMARY EXAMINER

Notice of References Cited	Application/Control No. 09/662,246	Applicant(s)/Patent Under Reexamination BERSON ET AL.	
	Examiner Matthew J Kremer	Art Unit 3736	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,126,613 A	10-2000	Edwards et al.	600/359
	B	US-6,170,058 B1	01-2001	Kausik	713/193
	C	US-4,942,877 A	06-1990	Sakai et al.	600/323
	D	US-5,842,977 A	12-1998	Lesho et al.	600/300
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 97/29678	08-1997	PCT	Osadchy et al.	A61B
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.